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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,160	04/23/2001	Kristiina Ylihonko	1574/49849	9775

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,160

Applicant(s)

YLIHONKO ET AL.

Examiner

Kathleen M. Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,6,12-22 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,12-17 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 2 and 18-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on February 20, 2004), Applicants filed a response and amendment received on August 17, 2004 and November 4, 2004. Said amendment cancelled Claims 1, 3, 4, 7-11, and 23-26, amended Claims 2, 5, 6, 12-14, 16-18, and 20-22 and added new Claims 27-29. Thus, Claims 2, 5, 6, 12-22, and 27-29 are pending in the instant Office action.

Election

2. As previously noted, Applicant's election with traverse of Group I, Claims 1-4, 7-11, and 16-22 in a paper filed on September 22, 2003 is acknowledged. This Group is drawn to "a DNA sequence related to the **full-length gene cluster** for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*, plasmids thereof, and methods of using said DNA" (emphasis added); the restriction requirement of record defines Groups I-XVIII (see written restriction requirement mailed June 12, 2003). Claims 2 and 18-22 are part of the elected invention and will be examined herein. Newly submitted or amended claims 5-6, 12-17 and 27-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

Claims 27-28 and 16-17, as amended, are neither drawn to the elected invention nor are drawn to a previously defined invention. Claim 27, for example, is drawn to 17 different inventions, that of *any* polynucleotide encoding *any* one of polypeptides SEQ ID NOs: 2-18. The complete gene cluster, as elected, encodes ALL of these polypeptides. The individual genes

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are distinct from the same reasons noted for Groups IV-XVIII in the original restriction requirement. These 17 inventions are considered new Groups XIX-XXXV, respectively.

New Claim 29 falls into original Group II and Group III.

Original Groups IV-XVIII, originally containing Claims 12-15, are reiterated below to contain amended Claims 12-15.

Group XXXVI (new). Claim 12, as relating to SEQ ID NO:2 (snogI) of Claim 27, is neither drawn to the elected invention nor is drawn to a previously defined invention. New Group XXXVI is herein assigned to this invention.

Group IV. Claims 12 and 15, as related to SEQ ID NO:3 (snogJ) of Claim 27.

Group V. Claims 12 and 15, as related to SEQ ID NO:4 (snogA) of Claim 27.

Group VI. Claim 12, as related to SEQ ID NO:5 (snoaM) of Claim 27.

Group VII. Claims 12 and 15, as related to SEQ ID NO:6 (snogN) of Claim 27.

Group VIII. Claim 12, as related to SEQ ID NO:7 (snoaG) of Claim 27.

Group IX. Claims 12 and 15, as related to SEQ ID NO:8 (snogC) of Claim 27.

Group X. Claims 12, 13 and 15, as related to SEQ ID NO:9 (snogK) of Claim 27.

Group XI. Claim 12, as related to SEQ ID NO:10 (snoaL) of Claim 27.

Group XII. Claim 12, as related to SEQ ID NO:11 (snoK) of Claim 27.

Group XIII. Claims 12 and 14, as related to SEQ ID NO:12 (snogD) of Claim 27.

Group XIV. Claim 12, as related to SEQ ID NO:13 (snoW) of Claim 27.

Group XV. Claims 12 and 14, as related to SEQ ID NO:14 (snogE) of Claim 27.

Group XVI. Claim 12, as related to SEQ ID NO:15 (snoL) of Claim 27.

Group XVII. Claim 12, as related to SEQ ID NO:16 (snoO) of Claim 27.

Group XVIII. Claim 12, as related to SEQ ID NO:17 (snoaF) of Claim 27.

Group XXXVII (new). Claim 12, as related to SEQ ID NO:18 (snoN) of Claim 27, is neither drawn to the elected invention nor is drawn to a previously defined invention. New Group XXXVII is herein assigned to this invention.

The pending restriction is drawn to Groups I-XXXVII. Since applicant has received an action on the merits for the originally presented invention (now Claims 2 and 18-22), this invention has been constructively elected by original presentation for prosecution on the merits (see 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

The restriction requirement is herein amended as noted above and remains FINAL since it is amended by virtue of Applicant's amendment to the claims. Claims 2, 5, 6, 12-22, and 27-

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29 are pending in the instant application. Claims 5, 6, 12-17, and 27-29 are withdrawn from further consideration as non-elected inventions. Claims 2 and 18-22 will be examined herein.

Priority

3. As previous noted, the instant application is granted the benefit of priority for the International Application No. PCT/FI99/00870 filed on October 20, 1999 and for foreign application 982295 filed in Finland on October 23, 1998.

Compliance with the Sequence Rules

4. Previous requirement for a statement for the record that the sequence listing filed in computer readable form and in paper copy on April 23, 2001 are the same is maintained to fully comply with the sequence rules. Applicant states that a copy of the originally filed statement is attached; no such attachment to the response received either August 17, 2004 or November 4, 2004 is found.

Withdrawn - Objections to the Specification

5. Previous objection to the specification for being unclear in the abbreviation "NAME" is withdrawn by virtue of Applicant's amendment.

Withdrawn - Objections to the Claims

6. Previous objection to Claims 1, 10, and 11 for typographical errors is withdrawn by virtue of Applicant's cancellation of said claims.

7. Previous objection to Claim 4 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's cancellation of said claim.

8. Previous objection to Claim 17 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment. Moreover, the Examiner notes that Claim 17 is now longer being examined as it has been amended to a non-elected invention.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1, 3, and 7-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "ant[h]racycline biosynthetic pathway" is withdrawn by virtue of Applicant's cancellation of said claims.

10. Previous rejection of Claims 2, 16, and 18-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "80% homology" is withdrawn by virtue of Applicant's amendment. Claims 2 and 18-22 are now limited to comprising exactly SEQ ID NO:1, Claim 16 is now drawn to a non-elected invention.

11. Previous rejection of Claims 7-11 and 18-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "hybrid compounds" is withdrawn by virtue of Applicant's amendment. Claims 7-11 have been cancelled; Claims 18-22 have had the term amended to read "polyketides", which term is clear from the art.

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12. Previous rejection of Claims 1, 3 and 7-11 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's cancellation of said claims.

13. Previous rejection of Claims 2, 16, and 18-22 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment. Claims 2 and 18-22 are now limited to comprising exactly SEQ ID NO:1, Claim 16 is now drawn to a non-elected invention.

14. Previous rejection of Claims 2, 16, and 18-22 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment. Claims 2 and 18-22 are now limited to comprising exactly SEQ ID NO:1, Claim 16 is now drawn to a non-elected invention.

15. Previous rejection of Claims 7, 8, 10, 11, 18, 19, 21, and 22 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claims and by virtue of persuasive arguments. The Examiner agrees that use of any *Streptomyces* host cell is enabled because the skilled artisan could test which would work readily and without undue experimentation.

New - Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 21-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are confusing by virtue of their dependence on Claim 2, full-length SEQ ID NO:1. In the specification, formula I is produced using pSY42 and formula II is produced using pSY15c (see pages 17-18). Thus, it is confusing how the full-length gene cluster has the same effect as these portions. Clarification is required.

Allowable Subject Matter

17. Claims 2 and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. Claims 2 and 18-20 are objected to and Claims 21-22 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

April 29, 2005